

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

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In re Patent Application of:  
Daniel G. Chain

Application No.: 10/084,380

Confirmation No.: 3496

Filed: February 28, 2002

Art Unit: 1649

For: **SPECIFIC ANTIBODIES TO AMYLOID  
BETA PEPTIDE, PHARMACEUTICAL  
COMPOSITIONS AND METHODS OF USE  
THEREOF**

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Examiner: G. S. Emch

**RESPONSE TO REQUIREMENT FOR ELECTION OF SPECIES**

MS Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

**I. Introduction**

This responds to the Office Action for the above-identified application that was mailed on August 19, 2008, and in which the Examiner set forth a requirement for the Applicant to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claims is finally held to be allowable.

**II. Interview Summary**

On August 19, 2008, Applicant's attorney, S. Peter Ludwig, spoke with Supervisory Examiner Stucker regarding the requirement for election of species. Examiner Stucker explained that the requirement was being imposed because certain claims newly added in the Amendment filed on May 19, 2008 specified different amyloid  $\beta$  peptides. It was explained to Examiner Stucker

that a search of subject matter embraced by the prior pending claims would have embraced the subject matter of the newly added claims. Examiner Stucker disagreed and indicated that the claims added in the Amendment filed on May 19, 2008 covered different subject matter and would require a new search and examination.

### **III. Response to Requirement for Election of Species**

The Examiner identified and required election between the following patentably distinct antibodies:

- a) An antibody which specifically binds to an epitope within residues 1-5 [of amyloid  $\beta$ ]; and
- b) An antibody which specifically binds to an epitope within residues 34-40 [of amyloid  $\beta$  1-40].

In response, Applicant provisionally elects an antibody which specifically binds to an epitope within residues 1-5 [of amyloid  $\beta$ ]. Claims 14, 19, 20, 25, 55, 56, 77, 78, 80, 83, 84, 86, 93-98 and 105-108 are believed to read on the elected species.

The requirement for election of a species is respectfully traversed on the grounds that it would not be a serious burden for the Examiner to examine all of the presently pending claims. Under Patent Office examining procedures, "if the search and examination of an entire application can be made without serious burden, the Examiner must examine it on the merits, even though it includes claims directed to distinct or individual inventions." *See* MPEP § 803. Here, the Examiner has already performed searches and conducted an examination that substantively extend to all of the pending claims. Claims 14 and 17 are directed in relevant part to antibodies specific for "a free N-terminus of amyloid  $\beta$  peptide or a free C-terminus of amyloid  $\beta$  peptide A $\beta$ 1-40." Claims 55 and 56 are directed to "a monoclonal antibody targeted to the free N-terminus of amyloid  $\beta$ , wherein the first amino acid of said N-terminus is aspartate at position 1 of amyloid  $\beta$ -peptide." Claims 75 and 77 are directed to an antibody "targeted to the free C-terminus of the amyloid  $\beta$ - peptide A $\beta$ 1-40." Claims 78 and 84 call for an monoclonal antibody "specific for an amyloid  $\beta$  peptide fragment that

begins with a pyroglutamate residue at position 3.” The antibody specificities set out in claims 14, 17, 55, 56, 75, 77, 78 and 84 have been present in the respective claims since at least an Amendment that was filed on June 30, 2006.

For more than two years, the Examiner has searched and examined claims in this application directed to antibodies that specifically bind epitopes including a free N-terminus at position 1 or position 3 of amyloid  $\beta$ . The searches required to examine these claims are co-extensive with the searches required to examine the antibody species that specifically binds to an epitope within residues 1-5. For more than two years, the Examiner has also examined claims in this application directed to antibodies that specifically bind epitopes including a free C-terminus of the amyloid  $\beta$ - peptide A $\beta$ 1-40. The searches required to examine these claims are co-extensive with the searches required to examine the antibody species that specifically binds to an epitope within residues 34-40. In short, the Examiner has already performed the searches required to examine the two species between which the Examiner now requires an election. Moreover, the Examiner has presented no rationale to support the contention that the species are likely to raise different issues under 35 U.S.C. §§ 101 and/or 112, first paragraph. In short, The Examiner has already effectively searched and examined both of the species identified in the Office Action. Since the search and examination has effectively been completed, it cannot be a “serious burden” for the Examiner to search and examine the complete application. The Examiner is therefore respectfully requested withdraw the requirement for election of a species.

#### **IV. Conclusion**

This application is believed to be in condition for allowance. A prompt and favorable Office Action on the merits of all pending claims is respectfully requested.

Dated: August 20, 2008

Respectfully submitted,

By /Mitchell Bernstein/  
Mitchell Bernstein  
Registration No.: 46,550  
DARBY & DARBY P.C.

Application No. 10/084,380  
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P.O. Box 770  
Church Street Station  
New York, New York 10008-0770  
(212) 527-7700  
(212) 527-7701 (Fax)  
Attorneys/Agents For Applicant